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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,970	08/04/2003	Satishchandra P. Patel	M0025.0293/P0293	4466
32172	7590	09/19/2007		
DICKSTEIN SHAPIRO LLP 1177 AVENUE OF THE AMERICAS (6TH AVENUE) NEW YORK, NY 10036-2714			EXAMINER TRAN, SUSAN T	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 09/19/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	<b>Application No.</b> 10/632,970	<b>Applicant(s)</b> PATEL, SATISHCHANDRA P.	
	<b>Examiner</b> Susan T. Tran	<b>Art Unit</b> 1615	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 11 September 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
 6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
 The status of the claim(s) is (or will be) as follows:  
 Claim(s) allowed: \_\_\_\_\_.  
 Claim(s) objected to: \_\_\_\_\_.  
 Claim(s) rejected: 1-20.  
 Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see detailed action.  
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.  
 13. ☐ Other: \_\_\_\_\_.

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## DETAILED ACTION

### *Response to Arguments*

Applicant's arguments filed 09/11/07 have been fully considered but they are not persuasive.

Applicant argues that Muyle reference points out, time and time again, that the monoester must be at least about 60% by weight. As discussed in paragraph 3 of the enclosed Declaration, Muyle teaches a composition containing less monoester is not storage stable. The passage on page 26, reference by the Examiner concerns compositions where the monoester is at least about 60% by weight. The Applicant surprisingly found that when the fatty acid had 8 to 10 carbon atoms and the monoester was less than 60 mole percent rather than greater than 60% by weight, the composition was storage stable.

In response to applicant's argument, the Declaration under 37 CFR 1.132 filed 09/11/07 is insufficient to overcome the rejection of claims 1-20 based upon Muyle et al. as set forth in the last Office action because: the teaching of Muyle of propylene glycol ester having a monoester content of at least about 60% permits one of ordinary skill in the art to, by routine experimentation select the monoester content of at least about 58%, or at least about 59%, which would fall within the claimed range of between 50-60%. The Declaration directed the examiner's attention to the comparative examples disclosed in the specification to show unexpected results over the prior arts, however, the examiner is unable to determine any unexpected result over the teaching of Muyle. This is because Mulye clearly teaches formulations with extensive advantageous results

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disclosed from page 26-28. The examples of Mulye show formulations that stayed clear (stable) even after more than three months. It is noted that differences in concentration *will not* support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is *critical*. When the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In the present case, applicant fails to show evidence that the difference in the concentration is critical to obtain a stable formulation. In contrast, Mulye teaches formulations that are stable even after more than three months. The teaching of Muyle of at least *about* 60% is within the optimum or workable ranges by routine experimentation. Accordingly, the 103(a) rejection over Muyle et al. is maintained.



SUSAN TRAN  
PRIMARY EXAMINER

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